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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/670,378

09/26/2003

Thomas DeWitt Smith

11051-0002

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22902

7590

03/08/2007

CLARK & BRODY

1090 VERMONT AVENUE, NW

SUITE 250

WASHINGTON, DC 20005

EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

10/670,378

**Applicant(s)**

SMITH, THOMAS DEWITT

**Examiner**

Renee Claytor

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 10-16, 22-25 and 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9, 17-21, 26, 27 and 37-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/26/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's election of Group II in the reply filed on February 7, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a))—and the restriction requirement is made FINAL.

### Claim Objections

Claims 17, 21 and 40 are objected to because of the following informalities:  
Claims 17, 21 and 40 depend on a non-elected claim. Appropriate correction is required.

### Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-9, 17-21, 26-27, and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (U.S. Patent 5,951,991).

Wagner et al. teach methods of making personal cleansing products with a conditioning emulsion base that contains an emulsifier capable of forming an emulsion between a water soluble phase and an oil phase (meeting the limitations of claims 6 and 17, Col. 14, lines 11-15). Oil soluble conditioning agents include petrolatum (Col. 15,

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lines 66-67 – Col. 16, lines 1-7) and the emulsifier includes methyl glucose dioleate (Col. 21, line 42). It is further taught that hydrocortisone is a preferred active ingredient (meeting the limitation of claims 9, 20, 26-27 and 37-38; Col. 23, line 59). Wagner et al. teaches that the conditioning emulsion is initially formulated by mixing the oil soluble agent and the emulsifier which is heated to from 70°C to 80°C (further meeting the limitation of claim 1; Col. 26, lines 18-29). It is taught that the preservative Glydant Plus (DMDM hydantoin and iodo propynyl butyl carbamate) is mixed with water and added to the water soluble phase which is then mixed in with the conditioning emulsion (meeting the limitation of claims 7, 18, 21, and 39-41; Col. 28, lines 25-30, 55-60). The active ingredient can also be added to the water soluble phase to be mixed in with the conditioning emulsion (Col. 28, lines 61-65).

Wagner et al. do not teach diluting the emulsion with water preheated to up to 50°C as stated in claims 8 and 19; however, it is obvious to vary and/or optimize the temperatures in the composition, according to the guidance provided by Wagner et al, to provide a stable emulsion. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Furthermore, it has been held that merely changing the order of steps in a multi-step process is not a patentable modification absent a showing of unexpected results. *Ex parte Rubin* 128 USPQ 440 (POBA 1959). Accordingly, one would be motivated to

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optimize the temperatures used in the composition of Wagner et al. in an effort to effectively incorporate water into the emulsion to provide a stable base.

Claims 6-9, 17-21, 26-27 and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Narula (US Patent 4,788,001) in view of McAtee et al. (US Patent 6,153,208).

Narula teaches methods of making oil-in-water emulsions that are comprised of petrolatum (Col. 3, lines 18-19) and PEG-120 methyl glucose dioleate (meeting the limitation of claims 6 and 17; Col. 6, line 48). Examples 11 and 12 detail an experiment in which an emulsion comprised of white petrolatum and PEG-120 methyl glucose dioleate were mixed together which was then diluted with water to provide the emulsion (meeting the limitation of claims 8 and 19). Narula teaches heating the oil phase prior to mixing to 75°C (Col. 9, lines 10-13).

Narula does not teach heating petrolatum up to 80°C, the addition of a preservative system (specifically DMDM hydantoin and iodo propynyl butyl carbamate), diluting the emulsion with water preheated up to 50°C , or the addition of hydrocortisone.

McAtee et al. teaches methods of making compositions with a conditioning emulsion comprised of an oil soluble conditioning agent, including petrolatum (Col. 25, line 58 and Col. 26, lines 13-21) and methyl glucose dioleate as the emulsifier (Col. 30, line 53). Active ingredients include hydrocortisone (meeting the limitation of claims 9, 20, 26-27 and 37-38; Col. 45, line 14 and Col. 48, line 8). Examples 6-10 state that the

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ingredients of the conditioning emulsion are mixed at between 75-115<sup>0</sup>C (further meeting the limitation of claims 6 and 17; Col. 54). Other ingredients that can be incorporated into the conditioning emulsion include Glydant Plus (meeting the limitations of claims 7, 21 and 39-41; Col. 47, lines 4-5).

Furthermore, it is obvious to vary and/or optimize the temperature to dilute the emulsion with water at 50<sup>0</sup>C provided in the composition, according to the guidance provided by McAtee et al., to provide a stable composition. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It has been held that merely changing the order of steps in a multi-step process is not a patentable modification absent a showing of unexpected results. *Ex parte Rubin* 128 USPQ 440 (POBA 1959). It would have been obvious to an ordinary person of skill in the art at the time of the invention to combine the teachings of Narula, which teaches an emulsion obtained by mixing petrolatum and methyl glucose dioleate that is diluted with water, with McAtee et al., which teach methods of making similar emulsions but teaching the addition of active ingredients and Glydant Plus. One would have been motivated to combine the two references because Narula teaches an emulsion base and McAtee et al. teach that additional components can be added without affecting the stability of the emulsion.

***Conclusion***

No claims are allowed.

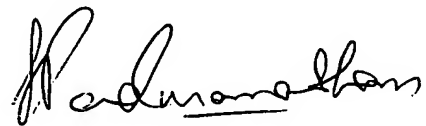
***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER